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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,778	08/21/2006	Mingyue He	MKC-005	2186

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GOODWIN PROCTER LLP
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EXAMINER

HORLICK, KENNETH R

ART UNIT	PAPER NUMBER
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1637

NOTIFICATION DATE	DELIVERY MODE
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11/14/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/549,778	Applicant(s) HE ET AL.	
	Examiner Kenneth R. Horlick	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-28 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 19-28 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/17/06</u> . | 6) <input type="checkbox"/> Other: ____. |

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1. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

2. Claims 19-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 19-28 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationship is: that the single primer used in PCR amplification targets the 5' consensus region sequence which is present at both the 5' and 3' ends of the single-stranded cDNA. Lacking this information, it cannot be understood how the claimed method functions. Clarification is required.

B) Claims 19-28 are confusing because it cannot be determined what sequence is "similar" to a 5' consensus region of the mRNA, as recited in independent claims 19 and 22. Clarification is required.

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C) Claims 19-28 are confusing because it cannot be determined what is encompassed by a “single primer type”; specifically, what is meant by “type”. It is submitted that the intended meaning would be clearer using the language “single primer” (i.e., deleting “type”). Clarification is required.

D) Claims 19-21 and 24-28 are confusing because “ribosome display complexes” is recited in the preamble of independent claim 19, but not in the active steps. It is suggested that this be clarified for purposes of consistency.

E) Claims 20 and 23 are further confusing because it is unclear what is meant by “single molecule” – this could mean either one molecule, or only one type of molecule. Clarification is required.

F) Claim 21 is further confusing because it is unclear what is meant by “optionally” in the recited context. Clarification is required.

G) Claim 26 is further confusing because it cannot be determined what primer is “similar to” the 5’ sequence of the RT primer. Clarification is required.

H) Claims 22-28 are further confusing because “ribosome complexes” is recited in step “a” of claim 22, while the preamble of claim 22 refers to “ribosome display complexes”. It is suggested that this claim be amended for consistency.

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3. Claims 19-28 are free of the prior art, but are rejected for other reasons. No claims are allowable. These claims require recovery of cDNA from mRNA in ribosome display complexes by: carrying out reverse transcription (RT) of said mRNA using an RT primer comprising a 5' sequence which is hybridizable to a 5' consensus region of the mRNA, and comprising a 3' primer region complementary to a 3' region of the mRNA, forming single stranded cDNA; and amplifying by PCR the single stranded cDNA using a single primer (which is complementary to the 5' consensus region sequence present at both ends of said single stranded cDNA). He et al. (1999) and Bieberich et al. teach recovery of DNA sequence from mRNA in ribosome display complexes, using conventional RT and PCR primers/strategies which lack the specific RT primer and single PCR primer required in the claims. Arnold et al. disclose the use of an RT primer which introduces a primer-binding site into cDNA to facilitate single-primer PCR amplification of double-stranded cDNA, but they do not teach or suggest using as this primer-binding site a 5' consensus region of the mRNA.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R. Horlick whose telephone number is 571-272-0784. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kenneth R Horlick/
Primary Examiner, Art Unit 1637

11/03/08